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Registration Decision

Boscalid

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Registration Decision for Boscalid

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Boscalid Technical Fungicide and Lance WDG Fungicide (formerly BAS 510 02F Crop Fungicide) and Cadence WDG Fungicide (formerly BAS 510 02F Turf Fungicide) containing the technical grade active ingredient boscalid to fungal control diseases in numerous agricultural crops and golf course turfgrass.

An evaluation of available scientific information found that, under the approved conditions of use, these products have value and do not present an unacceptable risk to human health or the environment.

These products were first proposed for full registration in the consultation document Proposed Registration Decision PRD2009-08, *Boscalid*. This Registration Decision describes this stage of the PMRA's regulatory process for boscalid and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-08. This decision is consistent with the proposed registration decision stated in PRD2009-08.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2009-08, *Boscalid* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value² when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the

¹ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

² "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Boscalid?

Boscalid is the active ingredient in the two end-use products, Lance WDG Fungicide and Cadence WDG Fungicide. These fungicides are used in agricultural crops and golf course turfgrass to control fungal diseases.

Health Considerations

Can Approved Uses of Boscalid Affect Human Health?

Boscalid is unlikely to affect your health when used according to the label directions.

Exposure to boscalid may occur through diet (food and water) or when handling and applying the product. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only the uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when products containing boscalid are used according to the label directions.

Boscalid Technical has low acute toxicity by the oral, skin and inhalation routes of exposure; it was minimally irritating to the eyes and slightly irritating to the skin. The formulated products, Lance WDG Fungicide and Cadence WDG Fungicide, have low acute toxicity by the oral, skin and inhalation routes of exposure and are mildly irritating to the eyes and minimally irritating to the skin. Results of the skin sensitization study for the technical grade active ingredient and the formulated products were negative, therefore, Lance WDG Fungicide and Cadence WDG Fungicide are not considered skin sensitizers.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and children, the subpopulation which would ingest the most boscalid relative to body weight, are expected to be exposed to less than 23% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from exposure to boscalid residues is not of concern for any of the population subgroups.

Animal studies revealed no acute health effects. Consequently, a single dose of boscalid is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established under the authority of the *Food and Drugs Act* through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Environmental Considerations

What Happens When Boscalid Is Introduced Into the Environment?

Boscalid enters the environment when used as a fungicide on agricultural crops and golf course turfgrass.

Boscalid is persistent in the environment. Although boscalid does have low mobility in soils, it may move to aquatic areas through spray drift or surface erosion. Boscalid was not acutely toxic to most of the terrestrial species tested, with the exception of vascular plants. Buffer zones have been implemented to mitigate this risk. Boscalid was found to be highly toxic to marine organisms. However, based on the use pattern for the end-use products, no risk to marine organisms was found. Boscalid was moderately toxic to fresh water aquatic species and based on the use pattern for the end-use products, a risk was determined; therefore, buffer zones were established for freshwater habitats.

Value Considerations

What Is the Value of Boscalid?

Boscalid controls fungal diseases in agricultural crops and golf course turfgrass.

Lance WDG Fungicide is used as a spray application to the foliage in several crops (canola, dry and succulent beans, lentils, chickpeas, berries group, bulb vegetables group, carrots, fruiting vegetables, grapes, field lettuce (head and leaf), potatoes, stone fruits group, strawberries, cucurbit vegetables, succulent and dried shelled peas and alfalfa grown for seed production) for the control of fungal diseases.

Cadence WDG Fungicide is used to control fungal diseases on golf course turfgrass.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the labels of Cadence WDG Fungicide and Lance WDG Fungicide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

- Because there is a concern with users having direct skin contact with Cadence WDG Fungicide and Lance WDG Fungicide, individuals must wear a long-sleeved shirt, long pants and chemical resistant gloves during mixing, loading, application, clean up and repair as well as goggles or a face shield during mixing/loading.

Environment

- Because there is a risk to freshwater aquatic organisms and terrestrial plants with the application of Cadence WDG Fungicide and Lance WDG Fungicide, appropriate buffer zones have been established and must appear on the product labels.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service.

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Reference: 2003, BAS 516 (BAS 510 F Plus BAS 500 F): Magnitude of the Residue on Spinach, Data Numbering Code: 7.4.1

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